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Registration Decision RD2012-06

Boscalid Seed Treatment

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Registration Decision for BAS 516 F ST

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Boscalid Technical Fungicide and BAS 516 F ST, containing the active ingredients boscalid and pyraclostrobin as a seed treatment, to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

The current registration decision addresses the major new use of boscalid as a seed treatment. A decision on the major new use of pyraclostrobin as a seed treatment is presented in Registration Decision RD2011-07, *Pyraclostrobin Seed Treatment*.

Boscalid Technical Fungicide and BAS 516 F ST were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-16, *Boscalid Seed Treatment*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for BAS 516 F ST and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-16. This decision is consistent with the proposed registration decision stated in PRD2011-16.

For more details on the information presented in this Registration Decision, please refer to PRD2011-16, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) as well as organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Boscalid?

Boscalid was first registered in 2003 in Lance WDG Fungicide as a foliar treatment for canola, legumes, and fruit and vegetable crops and in Cadence WDG Fungicide for turf use. Additional products have also been registered including Pristine WG Fungicide, which is a combination product containing both pyraclostrobin and boscalid for use on various crops and ornamentals. Boscalid inhibits spore germination, germ tube elongation and sporulation. Although it has systemic and curative properties, boscalid is intended as a preventative fungicide.

Health Considerations

Can Approved Uses of Boscalid Affect Human Health?

Potential exposure to boscalid may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when boscalid products are used according to label directions.

In laboratory animals, boscalid exhibited low acute toxicity by the oral, dermal and inhalation routes of exposure; it was minimally irritating to the eyes and slightly irritating to the skin. Boscalid was not a skin allergen.

The end-use product, BAS 516 F ST, is of low toxicity in rats via the oral, dermal and inhalation routes. It is not irritating to the eyes, but is mildly irritating to the skin of rabbits. It is a skin allergen in guinea pigs.

There was no indication that boscalid caused damage to the nervous system and there were no effects on reproduction. There was no evidence that the young animal was more sensitive to boscalid than the adult animal. In repeat dose studies, the target organ of toxicity was the liver.

Boscalid was not genotoxic (did not cause damage to DNA) in a battery of tests. Boscalid induced thyroid tumours in rats. Sufficient data were provided to determine a threshold for development of the tumours. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Occupational Risks From Handling BAS 516 F ST

Occupational risks from handling BAS 516 F ST are not of concern when label directions are followed.

Farmers and custom applicators have potential for exposure to pyraclostrobin and boscalid during mixing, loading and application as a seed treatment, and during bagging, loading and planting treated canola seed. The occupational exposure for these use scenarios is not of concern when the product is used according to the label directions.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years old, the subpopulation that would ingest the most boscalid relative to body weight, are expected to be exposed to less than 19% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from boscalid is not of concern for all segments of the population. There is no evidence that boscalid is carcinogenic; therefore, a cancer dietary exposure assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of boscalid is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

The MRLs for boscalid in/on canola and mustard (oilseed variety) have been established based on the data generated following foliar application use. The proposed seed treatment use of boscalid is not expected to result in residues exceeding their established MRLs.

Environmental Considerations

What Happens When Boscalid Is Introduced Into the Environment?

Environmental risks are not of concern when label directions are followed

Boscalid is introduced in the environment when it is used as a seed treatment in BAS 516 F ST. A limited exposure in soil and water is expected when boscalid is formulated as a seed treatment. However, birds and mammals may be exposed to this substance if they feed on treated seeds. A risk assessment has indicated that boscalid may cause adverse reproductive effects in birds if high numbers of seeds treated with BAS 516 F ST are ingested.

Value Considerations

What Is the Value of BAS 516 F ST?

BAS 516 F ST contains two active ingredients, pyraclostrobin and boscalid, that have broad range, complementary disease control spectra

Seed- and soil-borne pathogens cause diseases that manifest in reduced stands, poor seedling vigour and reduced yield and quality. Seed treatment fungicides increase the likelihood of producing healthy seedlings, which could contribute to improved yield.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of BAS 516 F ST to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading, calibrating, applying, bagging/stacking, cleaning/repairing treatment equipment and handling canola seed treated with BAS 516 F ST must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When planting treated seed, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When treating seed in commercial seed treatment facilities, closed transfer including closed mixing, loading, calibrating and closed treatment equipments must be used. Use of an open transfer system is allowed when treating seed on-farm only.

Environment

A precautionary label statement is included on the label to inform the user of the hazard to birds. Also, treated seeds that are spilled or exposed must be incorporated into the soil or cleaned-up from the soil surface.

Other Information

The relevant test data on which the decision is based (as referenced in Proposed Registration Decision PRD2011-16, *Boscalid Seed Treatment*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.